

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of The Effect of Purslane (Portulaca Oleracea) and Hollyhock Ointment on Pain and Episiotomy Wound Healing

Protocol summary

Study aim

Comparison of The Effect of Purslane (Portulaca Oleracea) and Hollyhock Ointment on Pain and Episiotomy Wound Healing

Design

In this study, the target population is the Women will be admitted to obstetrics and gynecology wards of Imam Reza and Umm al-Binin hospitals in Mashhad. Sampling method is also simple random, The sample size is 90 patients. This is a phase 3 clinical trial.

Settings and conduct

The location of this intervention is Ommolbanin and Imam Reza Hospital city of Mashhad. In this study, each intervention group used as much as one knuckle (2cm) Purslane, hollyhock and placebo ointment on episiotomy wounds twice per day for 10 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Pregnancy term (37-42), Singleton, Age 18 to 35 years old, nulliparous, Not having a particular diet, Having reading and writing skills, BMI less than 29 and voluntary participation. Exclusion criteria included: Hematoma, Infection, Disorders in the stages of labor (prolongation of labor and dystocia), Neonatal need for regeneration, Episiotomy extension, High hemorrhage after delivery, Use Vacuum, Repeated manipulation of the perineum, Not having any particular disease (anemia, cardiovascular disease, diabetes, immunity, liver, depression), Smoking and alcohol and drugs and Unwillingness to participate

Intervention groups

The intervention groups consist of three groups: the first group include 30 women than receiving topical Purslane ointment and the second group include 30 women than received topical Hollyhock ointment and the third group is the control group.

Main outcome variables

Pain, wound healing episiotomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190315043059N2**

Registration date: **2019-08-01, 1398/05/10**

Registration timing: **prospective**

Last update: **2019-08-01, 1398/05/10**

Update count: **0**

Registration date

2019-08-01, 1398/05/10

Registrant information

Name

Hamidreza Ebrahimisenu

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-06, 1398/05/15

Expected recruitment end date

2019-10-07, 1398/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The Effect of Purslane (Portulaca Oleracea) and Hollyhock Ointment on Pain and Episiotomy Wound Healing

Public title

Comparison of The Effect of Purslane (Portulaca Oleracea) and Hollyhock on Episiotomy Healing

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnancy term (42-37) Singleton Age 18 to 35 years old nulliparous Not having a particular diet Having reading and writing skills BMI less than 29 voluntary participation

Exclusion criteria:

Hematoma Infection Disorders in the stages of labor (prolongation of labor and dystocia) Neonatal need for regeneration, Episiotomy extension High hemorrhage after delivery Use Vacuum Repeated manipulation of the perineum Not having any particular disease (anemia, cardiovascular disease, diabetes, immunity, liver, depression) Smoking and alcohol and drugs Unwillingness to participate

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the number cruncher statistical system (NCSS) software, the samples will randomly assign to one of the three groups of Purslane ,hollyhock and control.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients become blind because of the appearance and color of the ointment. Due to lack of knowledge about the random allocation of patients to the intervention 1 and 2 group, the researcher was blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Asian Roads, Gonabad

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Razavi Khorasan

Postal code

9691987888

Approval date

2019-07-24, 1398/05/02

Ethics committee reference number

IR.GMU.REC.1398.065

Health conditions studied

1

Description of health condition studied

Episiotomy

ICD-10 code

ICD-10 code description

Second degree perineal laceration during delivery

Primary outcomes

1

Description

Pain intensity of episiotomy

Timepoint

Before intervention, 12 hours, 5 and 10 days postpartum

Method of measurement

Visual Analogue Scale

2

Description

wound healing of episiotomy

Timepoint

before intervention, 12 hours, 5 and 10 days postpartum

Method of measurement

REEDA scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Purslane ointment is used as much as one knuckle (2cm) on episiotomy wounds twice per day for 10 days.

Category

Treatment - Drugs

2

Description

Intervention group: Hollyhock ointment is used as much as one knuckle (2cm) on episiotomy wounds twice per day for 10 days

Category

Treatment - Drugs

3

Description

Control group: placebo ointment is used as much as one knuckle (2cm) on episiotomy wounds twice per day for 10 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ommolbanin Hospital

Full name of responsible person

Mohaddese Abbaspour

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Ayatolah Bahjat Street, Mashhad, Khorasan, Iran

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2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mohaddese Abbaspour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gonabad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Hamidreza Ebrahimisenu

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available